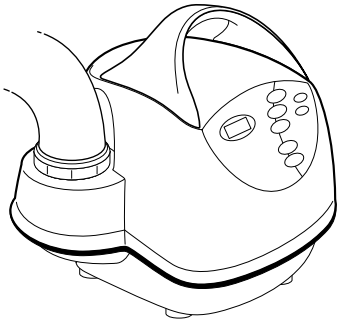
3M

Bair Hugger™

Normothermia System



Model 775 Warming Unit

Service Manual

(GB) 3M™ Bair Hugger™
Warming Unit Model 775

(FR) Appareil de réchauffement
Bair Hugger™ 3M™, modèle 775

(DE) 3M™ Bair Hugger™
Wärmeeinheit, Modell 775

3M

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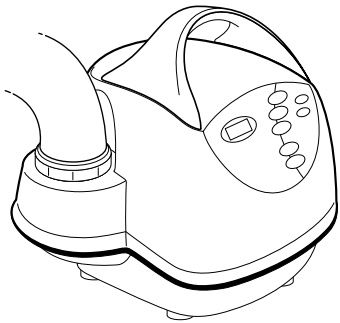

Model 775 Warming Unit

Service Manual

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Service Manual

Please forward to Biomedical Engineering Department

Introduction

Description of the 3M™ Bair Hugger™ Temperature Management System

The 3M™ Bair Hugger™ temperature management system consists of a Model 775 warming unit (with optional rolling stand, and other accessories) along with a 3M warming blanket, Bair Hugger warming gown, or the 3M™ Ranger™ 241 blood/fluid warming set.

The Bair Hugger warming unit is attached to the warming blanket or warming gown by means of a flexible hose. Warm air is generated in the warming unit and flows through the warming unit hose and into the blanket or gown. Depending on the model, the 3M blanket or gown is placed either around, over, or underneath the patient. Small perforations on the blanket or gown allow the warm air to be dispersed over the patient. For blood/fluid warming applications, the Model 241 blood/fluid warming set is inserted in the warming unit hose. When the warming unit is turned ON and a temperature setting is selected, warm air flows over the Model 241 tubing and warmed blood/fluid exits from the distal end of the tubing. For additional information on 3M blankets, gowns, the 241 warming set, or other accessories visit us online at bairhugger.com.

This manual includes operating and service instructions and warming unit specifications for the Model 775 warming unit. The warming unit can be used in all clinical settings where the patient may feel too warm or too cold. For information about using 3M blankets, gowns, or the 241 blood/fluid warming set with the warming unit, refer to the respective Instructions for Use.

Indications

The Bair Hugger temperature management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.

- The Bair Hugger temperature management system should only be used by trained medical professionals.
- Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

Definition of Symbols

The following symbols may appear on the product's labeling or exterior packaging.

An equipotentiality plug (grounded) conductor other than a protective earth conductor or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation. Please consult IEC 60601-1 for requirements.

Fuse

Type BF equipment (patient applied)

Date of manufacture

Manufacturer

VAC

Voltage, alternating current (AC)

This system is subject to European WEEE Directive 2002/96/EC. This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.

Protective earth ground

No free hosing

High fan setting

Low fan setting

Non-explosion proof

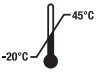
Consult instructions for use

Follow instructions for use

Recycle to avoid environmental contamination. This product contains recyclable parts. For information on recycling, please contact your nearest 3M Service Center for advice.

Attention; see instructions for use

Keep dry



Temperature limit

Explanation of Signal Word Consequences

⚠ WARNING:

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION:

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE:

Indicates a situation which, if not avoided, could result in property damage only.

⚠ CONTRAINDICATION: To reduce the risk of thermal injury:

- Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

⚠ WARNING: To reduce the risk of thermal injury:

- The Bair Hugger Model 775 warming unit has been designed to operate safely ONLY with 3M disposable warming products. Use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the warming unit being used in conjunction with non-3M products.
- Do not treat patients with the warming unit hose alone. Always attach the hose to a 3M warming blanket/gown before providing warming therapy.

- Do not allow the patient to lie on the warming unit hose.
- Do not allow the warming unit hose to directly contact the patient's skin during warming therapy.
- Do not leave neonates, infants, children and other vulnerable patient populations unattended during warming therapy.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy.
- Do not place the non-perforated side of the warming blanket/gown on the patient. Always place the perforated side (with the small holes) directly on top of the patient in contact with the patient's skin.
- Do not connect a torn or damaged blanket/gown to the warming unit.
- For over-body warming blankets and gowns; do not place patient securement device (i.e. safety strap or tape) over the warming blanket/gown.
- For underbody or side channel warming blankets; if a securement device (i.e. safety strap, tape) is used, en-sure the warming channels are not occluded.
- Do not place the warming blanket/gown directly over a dispersive electrode pad.
- Do not continue warming therapy if the red Over-temp indicator light illuminates and the alarm sounds. Unplug the warming unit and contact a qualified service technician.
- Do not continue 241 blood/fluid warming therapy if the red Over-temp indicator light illuminates and the alarm sounds. Immediately stop fluid flow, and discard the blood/fluid warming set. Unplug the warming unit, and contact a qualified service technician.
- For the Bair Hugger flex warming gown; ensure that the blood pressure cuff, ECG, IV or other lines or cords are not between the upper sleeve insert and the gown prior to deploying the upper sleeve warming insert(s), as this could result in tearing of the insert during deployment.
- Do not perform the over-temperature detection system test while the warming unit is being used for warming therapy.

⚠ WARNING: To reduce the risk of patient injury or death due to altered drug delivery:

- Do not use a warming blanket/gown over transdermal medication patches.

⚠ WARNING: To reduce the risk of injury due to interference with ventilation:

- Do not allow the warming blanket/gown or head drape to cover the patient's head or airway when the patient is not mechanically ventilated.

⚠ WARNING: To reduce the risk of injury due to patient falls:

- Do not use a warming blanket/gown to transfer or move the patient.

⚠ WARNING: To reduce the risks associated with hazardous voltage and fire:

- Keep power cord visible and accessible at all times. The plug on the power cord serves as the disconnect device.
- Only connect to outlets marked "Hospital only," "Hospital Grade," or a reliable grounded outlet.
- Use only the power cord specified for this product and certified for the country of use.
- Do not allow the power cord to get wet.
- Do not use the warming unit when it appears the unit, power cord or any component is damaged. Replace the warming unit. Contact 3M Technical Support.
- Do not disassemble the warming unit unless you are a qualified service technician. There are electrically live parts within the warming unit when it is connected to a power source.
- Connect each warming unit being tested to a separate power source.

⚠ CAUTION: To reduce the risk of cross-contamination:

- Except for specific Bair Hugger warming blanket models, 3M blankets/gowns are not sterile. Each warming blanket/gown is intended for single patient use ONLY. Placing a sheet between the warming blanket/gown and the patient does not prevent contamination of the product.
- Clean the warming unit and the outside of the warming unit hose after each patient use. See "Cleaning Instructions" on page 11.
- Follow applicable regulations when disposing of this warming unit or any of its electrical components.
- Do not attempt to clean the air filter as it may be contaminated from use. Discard the filter in a manner consistent with institutional protocol.
- Do not operate the Bair Hugger warming unit with the hose detached from the 3M warming blanket/gown. The Bair Hugger warming unit is intended to be used with the hose properly attached to its corresponding warming blanket/gown and in accordance with good practices for operating room sterile technique.

⚠ CAUTION: To reduce the risk of patient or caregiver injury:

- If mounted on an IV pole, the distance from the bottom of the warming unit to the floor must be less than 44" (112 cm) and the IV pole wheelbase diameter must be at least 28" (71 cm) to prevent tipping.

⚠ **CAUTION: To reduce the risk of fire:**

- 3M warming blankets and gowns are classified as Class I Normal Flammability as defined by the Consumer Product Safety Commissions flammable fabric regulation, 16 CFR 1610. Follow standard safety protocols when using high intensity heat sources.

⚠ **CAUTION: To reduce the risks of thermal injury, hyperthermia or hypothermia:**

- 3M recommends continuously monitoring core temperature. In the absence of continuous monitoring, monitor the temperature of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Monitor cutaneous responses of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Adjust air temperature or discontinue warming therapy when the therapeutic goal is reached, if elevated temperatures are recorded or if there is an adverse cutaneous response in the warmed area.
- Do not place the warming unit on a soft uneven surface, such as a bed, or a visibly wet surface as the air in-take may become blocked and cause the warming unit to overheat, compromising the warming unit's performance.
- Perform all temperature testing of the warming unit with a 3M Model 22110 temperature test unit.

⚠ **CAUTION: To reduce the risk associated with electromagnetic interference (EMI) due to portable and mobile radio frequency (RF) communications equipment:**

- The 3M Bair Hugger temperature management system has been tested to be resistant to both EMI and electro-static discharge (ESD).
- Install and put into service the 3M Bair Hugger temperature management system according to the electromagnetic compatibility (EMC) information provided in the Guidance and Manufacturer's Declaration.
- Should interference occur, move away from the portable or mobile RF communications equipment.

Notices

1. The Bair Hugger warming unit meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the warming unit to a different power source.
2. To avoid warming unit damage:
   - Use proper Electrostatic Discharge (ESD) procedures when performing maintenance.
   - Do not modify this equipment without authorization from the manufacturer.
   - Do not immerse the warming unit, warming unit parts or accessories in any liquid or subject them to any sterilization process.
   - Do not use cleaning solutions with greater than 80% alcohol or solvents, including acetone and thinner, to clean the warming unit or hose. Solvents may damage the labels and other plastic parts.

Proper Use and Maintenance

3M assumes no responsibility for the reliability, performance, or safety of the warming unit if the following events occur:

- Modifications or repairs are performed by unqualified personnel.
- The warming unit is used in a manner other than that described in the Operator's or Service Manuals.
- The warming unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.
- The warming unit not maintained in accordance with the procedures described in the Service Manual.

Read Before Servicing Equipment

All repair, calibration, and servicing of the warming unit require the skill of a qualified, medical equipment service technician who is familiar with good practice for medical device repair. If service does not require the manufacturer's attention, the Model 775 Service Manual provides the technical information needed to service the warming unit. Perform all repairs and maintenance in accordance with the instructions in the Service Manual. For additional service information, please contact 3M technical support.

Safety Inspection

Perform a safety inspection after making repairs to the warming unit and before returning the warming unit to service. A safety inspection should include calibrating the operating temperature settings and testing the over-temperature detection function as described in this service manual as well as testing for leakage current and continuity check on safety ground.

Warming Unit Overview

When you connect the warming unit to a grounded power source, the warming unit automatically performs the power-on-reset operation described below. Following the power-on-reset operation, the warming unit will enter the *Standby* mode. You can select any operating mode by pressing the appropriate button on the warming unit control panel. See Figure 1.

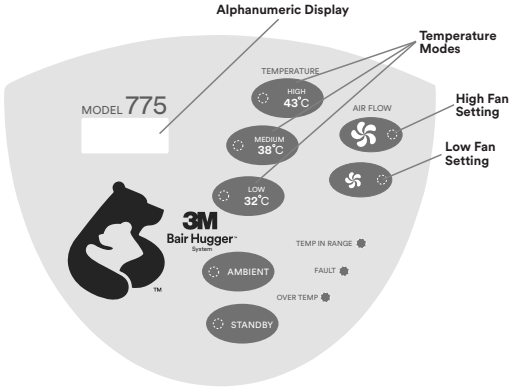


Figure 1. MODEL 775 WARMING UNIT Control panel

Warming Unit Power-On-Reset

The warming unit automatically performs the following power-on-reset sequence after you connect the warming unit to a properly grounded power source (See Figure 1):

- Performs all self-test functions.
- Illuminates indicator lights and all pixels in the alphanumeric display momentarily.
- Displays the text *"MD 700's"* and the software revision level in the alphanumeric display.
- Sounds the alarm (three low-level clicks).
- Enters the *Standby* mode with the *high fan* setting selected by default.

NOTE: The *low fan* setting indicator light will not illuminate during power up.

If the warming unit loses power for less than 1 second, the warming unit software will return the warming unit to the operating mode you selected prior to the power loss. However, if the warming unit loses power for longer than 1 second, the warming unit software will reset when you restore power. The warming unit will then enter the *Standby* mode with the *high fan* setting selected by default.

Temperature Modes

The warming unit has 4 operating modes: *Ambient, 32°C, 38°C, 43°C*.

To select the *32°C, 38°C, 43°C,* or *Ambient* mode, press the corresponding button. The warming unit will operate within the specified temperature range, shown in the table below.

TEMPERATURE MODE	TEMPERATURE OF DELIVERED AIR
32°C	32°C ± 1.5°C
38°C	38°C ± 1.5°C
43°C	43°C ± 1.5°C
Ambient	Warming unit will supply air at room temperature

After you select a temperature mode, the following events occur:

- Corresponding temperature indicator light illuminates.
- Blower operates at selected fan speed.
- Heater activates except in *Ambient* mode.
- Temperature mode timer and hour meter activate.
- Temperature at the blanket-end of the hose appears in the alphanumeric display.
- *Temp in Range* indicator light illuminates when the temperature at the blanket end of the hose is within ±1.5°C of the selected setting; this indicator light does not illuminate in the Ambient mode.

Airflow Modes

The warming unit has two preset fan speed settings: a default or *high fan* setting ( ) and a reduced or *low fan* setting ( ). The warming unit will reset/default to the *high fan* setting each time the warming unit is powered up or *Standby* is selected. The *low fan* setting () may be preselected while in *Standby* prior to selecting the desired temperature.

Standby Mode

To place the warming unit in *Standby* mode, press the **Standby** button. When in Standby mode, the following events occur:

- *Standby* indicator light illuminates.
- Blower and heater are turned OFF.
- Alphanumeric display deactivates.
- Alarm and fault detection functions remain active.
- Operating timer pauses.
- Airflow mode resets/defaults to the *high fan* setting.

Fault Conditions

The warming unit software recognizes several nonhazardous fault conditions including:

- Sensor failures
- Heater failures
- Computer failure
- Software failure
- Keypad failure
- Power supply failure
- Blower motor failure
- Forced over-temperature test failure

When a fault condition exists, the following events occur:

- Fault indicator light flashes.
- Audible alarm sounds.
- Blower and heater turn off.
- Fault code appears in the alphanumeric display.
- Up to 5 fault codes are stored in memory.

When the audible alarm sounds, press any button on the keypad to silence it. The warming unit must be unplugged before it can be restarted. See "Viewing the Fault Code Log" on page 8 and the "Fault Code Table" on page 9 for more information about specific fault codes.

Over-Temperature Condition

When an over temperature condition exists, the following events occur:

- *Over-temp* indicator light flashes.
- Audible alarm sounds.
- Blower, heater, and operating mode indicator lights automatically turn off.
- Fault code appears in the alphanumeric display (see page 9).

When the audible alarm sounds, press any button on the keypad to silence it. The warming unit must be unplugged before it can be restarted.

Alternative Modes

The warming unit has 5 alternative modes that allow access to the service and calibration utilities of the warming unit (see Figure 2 on page 7).

ALTERNATIVE MODES	DESCRIPTION
AltMode0	Hour Meter
AltMode1	Calibration
AltMode2	Fault Code Log
AltMode3	System Information
AltMode4	Over-temperature Detection Test

The *Hour Meter* mode displays the cumulative amount of operating time (in *Ambient, 32°C, 38°C, and 43°C* modes) the warming unit has been in use. The time is displayed in whole hours only.

The *Calibration* mode allows a technician to check and adjust the hose end sensor calibration offset value. This should be done as part of routine maintenance and after servicing the warming unit or replacing the hose. The hose end sensor temperature can be altered a maximum of ±3.0°C by adjusting the calibration offset value. In the *Calibration* mode, the warming unit operates in the *Ambient* temperature mode, and the alphanumeric display shows the current hose end sensor temperature and calibration offset with 0.1°C precision.

The *Fault Code Log* mode sequentially displays the last 5 fault codes stored in system memory. Please refer to the "Fault Code Table" on page 8 for more information about a particular fault code.

The *System Information* mode allows the technician to view important system information including the firmware, system identification, serial port baud rate, 5V power supply status, and the control board serial number.

The *Over-temperature Detection Test* mode allows the user to test the operation of the independent over-temperature shutdown system.

Accessing the Alternative Modes

To access the alternative modes, you must press the *Alternative Mode* button that is located on the front panel of the warming unit but is unlabeled. Press the center of the Bair Hugger logo when the instructions direct you to press the *Alternative Mode* button.

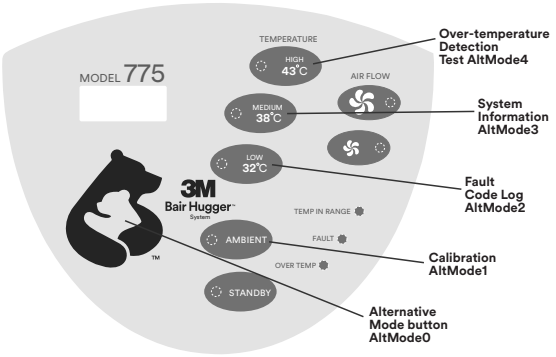


Figure 2. Location of Alternative Mode button

To enter one of the *alternative* modes, press the *Alternative Mode* button in combination with one of the operating mode buttons, also located on the front panel. Figure 2 indicates which keys must be pressed to enter each of the 5 *alternative* modes. When the correct combination of keys is pressed, the display reads *"Hold for AltModeX,"* where "X" represents the selected *alternative* mode.

Exiting an Alternative Mode

Exit the alternative modes by pressing the *Alternative Mode* button or by waiting for 60 seconds. You will need to access the *alternative* modes for several of the service procedures described in this manual.

Required Preventative Maintenance

Note: Auto tester must not interrupt the voltage during warming unit on power reset or an Error 053/054 may result.

Calibrating the Operating Temperature

⚠ **Caution:** Perform all temperature testing of the warming unit with a 3M Model 22110 temperature test unit.

3M assumes no responsibility for the reliability, safety, or performance of the Bair Hugger temperature management system if temperature tests or adjustments are made in any manner other than those described here. Improper measurement or adjustment of the warming unit's normal operating temperature could result in patient exposure to temperatures outside of the indicated range and may lead to patient injury.

Service frequency

Every 6 months or 500 hours of use, or whenever service is performed.

Tools/equipment

Model 22110 temperature test unit

Calibrated thermocouple temperature monitor

NOTES:

- The Model 22110 temperature test unit simulates the operating characteristics of 3M warming blankets and gowns when used with Bair Hugger warming units.
- When using the Model 22110 temperature test unit, take temperature readings using a calibrated thermometer that can accept a male, subminiature connector and read a "K" style thermocouple (e.g., a Fluke Model 52 K/J Thermometer). If the test unit connector does not fit your thermometer, remove the connector from the test unit and attach a connector that fits your meter. Be certain to observe polarity.

METHOD

Note: If the warming unit has been stored at a temperature lower than 20°C, allow it to reach ambient temperature before beginning the calibration procedure.

1. Attach the Model 22110 temperature test unit to the end of the warming unit hose.
2. Connect the warming unit to a grounded power source. The warming unit performs a self-test and automatically proceeds to *Standby* mode.
3. Press the *Ambient* button to place the warming unit in *Ambient* mode. Allow the warming unit to run in *Ambient* mode for at least ten minutes to equalize the temperature of the warming unit's internal components.

   NOTE: Verify warming unit is set to *high fan* setting by ensuring the indicator light next to the upper fan is illuminated.
4. Press the *Alternative Mode* button (see Figure 2. Location of Alternative Mode button on page 7) and the *Ambient* button simultaneously for 3 seconds. The warming unit is now in *Calibration* mode. In this mode, the warming unit performs the following tasks:
   - *32°C* and *38°C* indicator lights flash indicating they can be used to adjust the offset value.
   - Blower remains on.
   - Heater elements remain off.
   - The text *TMP* and the end of hose temperature in °C (0.1°C resolution) appear in the alphanumeric display.
   - The text *OS* and the current calibration offset value (0.1°C resolution) appear in the alphanumeric display.
5. Compare the temperature shown on the alphanumeric display and the temperature shown on the thermocouple monitor.
   - If the temperatures match, no adjustment is necessary, press the Alternative Mode button to return the warming unit to Standby mode.
   - If the temperatures do not match, adjust the warming unit displayed temperature:
     a. Press the *32°C* button to decrease the temperature or the 38°C button to increase the temperature by 0.1°C. You can adjust the temperature of the warming unit a maximum of ±3°C.
     b. Continue to press the *32°C* or *38°C* button(s) until the temperature in the alphanumeric display matches the temperature on the thermocouple monitor as close as possible.
     c. Press the *Alternative Mode* button to store the calibration offset value and return the warming unit to *Standby* mode.

Note: If it is necessary to enter an offset value greater than ±3°C, there may be a defect in the warming unit hose end sensor. Remove warming unit from service until a new hose assembly can be substituted.

Testing the Over-Temperature Detection System

⚠ **Warning:** Do not perform the over-temperature detection system test while the warming unit is being used for warming therapy.

⚠ **Caution:** Perform all temperature testing of the warming unit with a 3M Model 22110 temperature test unit.

⚠ **Caution:** Connect each warming unit being tested to a separate power source.

SERVICE FREQUENCY

Every 6 months or 500 hours of use, or whenever service is performed.

TOOLS/EQUIPMENT

Model 22110 temperature test unit

Calibrated thermocouple temperature monitor

Method

Note: If continuing from the previous section (Calibrating the Operating Temperature) skip to step 4.

Note: If the warming unit has been stored at a temperature lower than 20°C, allow it to reach ambient temperature before beginning the test.

1. Connect the warming unit to a grounded power source. The warming unit performs a self-test and automatically proceeds to Standby mode.
2. Connect the temperature test kit to the hose of the warming unit.
3. Press the *Ambient* button and allow the warming unit to run for 5 minutes.

NOTE: Verify warming unit is set to the *high fan* ( ) setting by ensuring the indicator light by the upper fan is illuminated.

4. With the warming unit in *Ambient* mode, press the *Alternative Mode* button (See Figure 2. Location of Alternative Mode button on page 7) and the 43°C button simultaneously for 3 seconds. The warming unit is now in the *Over-Temperature Detection* Test mode. In this mode, the warming unit performs the following tasks:
   - Blower remains ON.
   - Heater elements turn ON at full power.
   - *43°C* indicator light flashes.
   - Over-temperature timer activates.
   - *OT Test* flashes in the alphanumeric display.
5. Wait for the warming unit to perform the over-temperature test. When the test is complete, the warming unit performs the following tasks:
   - Heater elements turn OFF.
   - Blower continues to operate. (**NOTE:** The blower turns off if an over-temperature condition occurs during normal use.)
6. View the alphanumeric display to determine test outcome:
   a. PASS–The warming unit detected an over-temperature condition within 150 seconds. An alarm sounds for 2 short beeps. The text “PASS” flashes in the alphanumeric display, followed by these messages:
      i. *OT Test - PASS-Prx* or *OT Test - PASS-Dst*
      ii. *TestTime - XX Secs*
      iii. *Unplug - To Reset*
   b. FAIL–Warming unit did not detect an over-temperature condition within 150 seconds (time-out failure). An alarm sounds and the *Fault* indicator light flashes. The text *FAIL* flashes in the alphanumeric display, followed by these messages:
      i. *OT Test - FAIL*
      ii. *TestTime - 150 Secs*
      iii. *Unplug - To Reset*

Note: Do not place a warming unit back into service if it fails the over-temperature test. Contact 3M technical support.

7. Record the maximum temperature displayed by the test kit. (Use Maintenance Log on page 17.) If the temperature is outside the range of 46°C to 56°C, contact 3M technical support for further instructions.
8. After the test is complete, allow the warming unit to cool by running it for at least five minutes.
9. Unplug the warming unit to reset it to normal operation.

Viewing the Fault Code Log

SERVICE FREQUENCY

As often as necessary.

TOOLS/EQUIPMENT

None required.

METHOD

1. If your warming unit is already ON, you can access the fault code log from any operating mode. Otherwise, connect the warming unit to a grounded power source. The warming unit performs a self-test and automatically proceeds to Standby mode. Then select any operating mode.
2. Press the *Alternative Mode* button (Figure 2. Location of Alternative Mode button on page 7) and the 32°C button simultaneously for three seconds. The warming unit is now in Fault Code Log mode. In this mode, the warming unit performs the following tasks:
   a. Continues to operate in current operating mode.
   b. 32°C and 38°C indicator light flashes.
   c. Text *FC(n) XXX* appears in the alphanumeric display. *FC* is an abbreviation for the phrase fault code *n* represents the numerical order of the fault code in the log, and *XXX* represents the code for the fault condition. See page 9 for a list of fault codes and their meanings.
   d. The time (HH:MM:SS) of each fault appears below *FC(n) XXX* in the alphanumeric display. If the warming unit reaches 100 or more hours the time only reads hours and minutes.
3. Press either the *32°C* or *38°C* button to view the next fault code in the log. The warming unit stores a maximum of 5 fault codes in non volatile memory.
4. Press the *Alternative Mode* button to return the warming unit to its previous operating mode.

Clearing the Fault Code Log

Put the warming unit in *Fault Code* mode by pressing the *Alternative Mode* button and the *32°C* button simultaneously for three seconds; then, press the *43°C* button.

NOTE: The fault code log should not be cleared unless instructed to do so by a 3M representative.

Fault Code Table

The software will detect and report the following conditions by displaying the corresponding fault code:

FAULT CONDITION	FAULT CODE
Internal sensor 1 over-temperature condition	001
Hose end sensor 2 over-temperature condition	002
Hose end sensor 3 over-temperature condition	003
Internal sensor 1 shorted	004
Hose end sensor 2 shorted	005
Hose end sensor 3 shorted	006
Hose end sensor 2 open	007
Rapid button press, blower failure, open thermostat or low wattage heater failure	008
Open thermostat/medium wattage heater failure	009
High wattage heater failure	010
A/D converter timeout	011
A/D startup check failed	012
(Reserved Fault Code)	013
Error in execution loop	014
Timeout on alphanumeric display busy flag clearing	015
RAM corruption in duplicate RAM locations	016
Error in executing a depressed key	017
Stuck key during startup	050
EEPROM is at max # write cycles	051
Non-0 EEPROM byte detected after zeroing	052
EEPROM checksum failure on copy #1 (see page 11)	053
EEPROM compare failure copy #1 to copy #2	054
EEPROM compare failure copy #1 to RAM	055
EEPROM write cycle time out	056
SPI byte transfer time out	057
EEPROM write error when entering standby	059
Real time clock failure	060
Temperature out of range high	070
Temperature out of range low	071
5 V power supply in excess of 5.333 V	100
5 V power supply under 4.667 V	101
Startup test EEPROM error	102
Startup test RAM error	103

Viewing the Hour Meter

SERVICE FREQUENCY

As often as necessary.

TOOLS/EQUIPMENT

None required.

METHOD

1. If your warming unit is already ON, you can begin the test from any operating mode. Otherwise, connect the warming unit to a grounded power source. The warming unit performs a self-test and automatically proceeds to *Standby mode*. Then select any operating mode.
2. Press the *Alternative Mode* button for 3 seconds. (See Figure 2. Location of Alternative Mode button on page 7.) The warming unit is now in *Hour Meter Display* mode. In this mode, the warming unit performs the following tasks:
   a. Continues to operate in current operating mode.
   b. *Hours* appears in the alphanumeric display.
   c. Cumulative hours of warming unit operation appear in the alphanumeric display. The time is displayed in whole hours only.
3. Wait 60 seconds or press the *Alternative Mode* button to return the warming unit to its previous operating mode.

Viewing the Operating Timer

To view the amount of time the warming unit has been operating in the current temperature mode, press and hold the current temperature mode button for at least 3 seconds. The time is displayed in HH:MM:SS format.

Replacing the Air Filter

SERVICE FREQUENCY

Every 12 months or 500 hours of use.

TOOLS/EQUIPMENT

Replacement air filter

#2 Phillips screwdriver

⚠ **Caution:** Do not attempt to clean the air filter as it may be contaminated from use. Discard the filter in a manner consistent with institutional protocol.

Method

1. Disconnect the warming unit from the grounded power source.
2. Turn the warming unit upside down.
3. Remove the 2 screws located in the louvered filter cover.
4. Lift the filter cover off the warming unit.
5. Remove the air filter and discard it.
6. Place the new filter in the filter compartment with the gasket toward the filter ledge.
7. Replace the filter cover with the louvers facing the back of the warming unit.
8. Replace the 2 screws in the filter cover.

Replacing the Hose

SERVICE FREQUENCY

As needed.

TOOLS/EQUIPMENT

Replacement hose

Needle-nose pliers

Strap wrench

METHOD

Detaching Warming Unit Hose

1. Disconnect the warming unit from the power source before replacing hose.
2. Unscrew the hose collar.
3. Slide the hose out of the warming unit. The hose will still be attached to the warming unit by a cable.
4. By hand or using a needle-nose pliers, carefully detach the cable connector from the header plug located inside the hose connector (see Figure 3. Hose replacement).

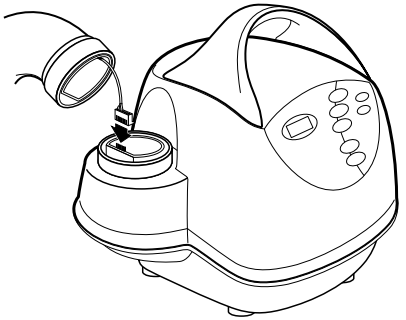


Figure 3. Warming Unit Hose Replacement

Reattaching Warming Unit Hose

1. Attach the cable connector of the new warming unit hose to the header plug, making sure that the protrusions on the connector align with the corresponding slots on the header.
2. Align the flat section of the warming unit hose end with the corresponding flat part of the warming unit's hose connector and slide the replacement hose into the warming unit.
3. Firmly screw the hose collar back into place.
4. Reconnect the warming unit to a grounded power source.
5. Calibrate operating temperature settings. See page 7.
6. Perform over-temperature detection system test. See page 8.

Replacing the Fuses

SERVICE FREQUENCY

As needed.

⚠ **Warning:** Do not disassemble the warming unit unless you are a qualified service technician. There are electrically live parts with-in the warming unit when it is connected to a power source.

Notice: Use proper Electrostatic Discharge (ESD) procedures when performing maintenance. Failure to do so may result in damage to the warming unit.

TOOLS/EQUIPMENT

Phillips screwdriver

Wire cutter

Wire tie

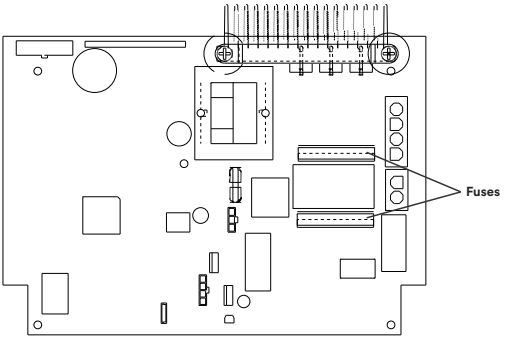
Needle-nose pliers

METHOD

1. Detach the warming unit hose (see Detaching Warming Unit Hose on page 9 for instructions).

Disassembling the Warming Unit

1. Turn warming unit upside down.
2. Using a Phillips screwdriver, remove the eight screws that secure the top and bottom enclosures together
3. Turn warming unit upright.
4. Remove four screws that attach upper enclosure to back plate.
5. Lift the upper enclosure straight up and disconnect the user interface wire by squeezing the release tabs.
6. Replace fuses.



Reassembling the Warming Unit

1. Slide the upper enclosure over the chassis.
2. Reinstall the four enclosure screws to attach the upper enclosure to the back plate. Push down on the top of the warming unit when tightening the screws to attain proper sealing of the enclosures.
3. Flip the warming unit upside down and replace the eight enclosure screws. In order to obtain a proper seal and prevent noise, be sure to tighten these screws fully. If using a power screwdriver, you may need to increase the torque setting to ensure proper seating. Once complete, if there is a whistling noise present it is most likely from these screws not being fully tightened.
4. Reattach the warming unit hose (see Reattaching Warming Unit Hose on page 10 for instructions).

Cleaning, Maintenance and Storage

Cleaning Instructions

1. Disconnect the warming unit from the power source before cleaning.
2. Cleaning should be performed in accordance with hospital practices for cleaning OR equipment. After every use; wipe the warming unit, the outside of the warming unit hose, and any other surfaces that may have been touched. Use a damp, soft cloth and a hospital approved mild detergent, germicidal disposable wipes, disinfecting towelettes, or antimicrobial spray.
3. Let air dry or dry with a separate clean soft cloth.

Notice:

Do not use cleaning solutions with greater than 80% alcohol or solvents, including acetone and thinner, to clean the warming unit or hose. Solvents may damage the labels and other plastic parts.

Do not immerse the Bair Hugger warming unit, warming unit parts, or accessories in any liquid or subject them to any sterilization process.

SERVICE FREQUENCY

As needed.

STORAGE

Store all components in a cool, dry place when not in use.

Troubleshooting

The warming unit software routinely checks unusual operating conditions. If such a condition occurs, the system may trigger a fault condition and alarm. The warming unit can be reset by disconnecting the warming unit from the main power source and allowing 30-60 seconds for the system to reset. If the fault code condition reoccurs, disconnect again and wait 5 minutes for the system to reset. If the fault condition reoccurs upon connection to the main power source, the warming unit may have a hard-fault or permanent error. Contact 3M technical support. If the fault does not reoccur upon connection to the main power source, the warming unit may have a cautionary fault.

PERMANENT ERRORS – A FAULT CONDITION ALWAYS OCCURS AT TURN ON OR AFTER PRESSING A TEMPERATURE SETTING

FAULT CODE	POSSIBLE CAUSE	SOLUTION
FC-001 FC-002	Faulty hose end sensor at patient end.	Replace warming unit hose. Refer to service manual or IFU included with replacement part for instructions.
FC-003 FC-004	Faulty elbow sensor.	Replace elbow sensor. Refer to IFU included with replacement part for instructions.
FC-005 FC-006 FC-007	Warming Unit Hose disconnected from warming unit (FC-007 only).	Reattach warming unit hose. Calibrate and return to service.
FC-008 FC-009 FC-010	Faulty heater element or faulty control board.	Verify fan runs in ambient. Check resistance of J4 connector on control board. The resistance may be up to 400 Ohms. White to black White to blue White to yellow If “open”, replace heater. Otherwise, replace control board. Calibrate and return to service.
FC-050	Defective user interface.	Replace user interface. Calibrate and return to service.
FC-053, 054	EEPROM error.	Reset microprocessor. (Press and hold Alternative Mode button and Standby buttons at same time then connect to power source. Release buttons when Standby light remains on). Calibrate and return to service.
FC-100 FC-101	Defective control board.	Replace control board. Calibrate and return to service.

CAUTIONARY ERRORS – FAULT CONDITION WHILE UNIT IS IN USE

FAULT CODE	POSSIBLE CAUSE	SOLUTION
FC-001 FC-003 FC-008	Airflow occluded.	Disconnect from power source. Remove warming unit hose occlusion. Position hose end correctly into hose card (refer to the Operator's Manual). Check for air intake obstructions on the bottom of the warming unit. Replace filter. Wait 30-60 seconds before reconnecting to the main power source. If no fault occurs, warming unit is ready for use.
	Intermittent elbow sensor failure.	Disconnect from power source. Allow warming unit to cool. Wait 30-60 seconds before reconnecting to the main power source. If these faults continue to occur during use and the airflow is not occluded replace elbow sensor.
FC-002 FC-003 FC-004 FC-005 FC-006 FC-007	Warming unit hose end sensor failure at patient end. Moisture. Intermittent hose sensor failure. High heat.	Disconnect from power source. Allow warming unit to cool. Wait 30-60 seconds before reconnecting to the main power source. If no fault occurs, warming unit is ready to use. If these faults continue to occur during use, replace hose.
	Intermittent elbow sensor failure.	Disconnect from power source. Allow warming unit to cool. Wait 30-60 seconds before reconnecting to the main power source. If these faults continue to occur during use and the airflow is not occluded replace elbow sensor.
FC-070	Warming unit hose end temperature exceeds the set point by at least 5°C for approximately 5 minutes. Faulty control board.	Unplug the warming unit, then wait 30-60 seconds before reconnecting to the main power source. If no fault occurs, warming unit Is ready to use. Replace control board. Calibrate and return to service.
FC-071	Warming unit hose end temperature is at least 10°C below the set point for approximately 10 minutes. Faulty control board. Faulty heater. Faulty blower.	Unplug the warming unit, then wait 30-60 seconds before reconnecting to the main power source. If no fault occurs, warming unit Is ready to use. Replace control board. Replace heater. Replace blower. Calibrate and return to service.
Whistling sound during operation	Air leaks in enclosure or warming unit hose. Faulty bearing in blower motor.	Tighten all screws. Check for holes in warming unit hose. Check for loose warming unit hose collar and presence of O-rings. Clean the filter gasket and mating surface.

Technical Support and Order Placement

USA

TEL: 800-733-7775

OUTSIDE OF THE USA

Contact your local 3M representative.

When You Call for Technical Support

We will need to know the serial number of your Bair Hugger warming unit when you call us. The serial number label is located on the back of the warming unit.

In-Warranty Repair and Exchange

USA

Call 3M technical support if your warming unit requires factory service. A technical support representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your warming unit. Your technical support representative will also send a shipping carton to you at no charge, if needed. Call your local supplier or sales representative to inquire about borrowing a warming unit while we service your warming unit.

OUTSIDE THE USA

Contact your local distributor concerning in-warranty repair and exchange.

Returning Warming Units for Service

TOOLS/EQUIPMENT

3M service carton

Tape dispenser

Shipping label

Marking pen

METHOD

1. Call 3M technical support (see page 12 for contact information) to get a Return Authorization (RA) number and a service carton.
2. Remove the top foam piece. If the plastic liner is available, use it to enclose the warming unit.
3. Lower the warming unit carefully into the carton.
4. Replace the top foam piece. Observe proper orientation. Hose will extend out in the corner of foam.
5. Lay the warming unit hose on top of the foam piece around the edge.
6. Seal the carton with tape.
7. Apply the shipping label addressed to 3M Health Care.
8. Write the RA number on the outside of the carton.
9. Ship to 3M Health Care.

Specifications

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 775 warming unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 775 warming unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 775 warming unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 775 warming unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 775 warming unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 775 warming unit should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line(s) to earth	±1 kV line to line ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 775 warming unit requires continued operation during power mains interruptions, it is recommended that the Model 775 warming unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 775 warming unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 775 warming should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Model 775 warming unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 775 warming unit is used exceeds the applicable RF compliance level above, the Model 775 warming unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 775 warming unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Model 775 warming unit			
The Model 775 warming unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 775 warming unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 775 warming unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Physical Characteristics

DIMENSIONS
13” high x 13” deep x 14” wide (33 cm high x 33 cm deep x 36 cm wide)

WEIGHT
16 lb (7.3kg)

RELATIVE NOISE LEVEL
53 dBA (High fan setting)

48 dBA (Low fan setting)

HOSE
Flexible, compatible with the Model 241 blood/fluid warming set.

Length: 80” (203 cm)

UNIT INTAKE FILTER
MERV 14*

** See Frequently Asked Questions on Filtration (p. 58)*

RECOMMENDED FILTER CHANGE
Every 12 months or 500 hours of use

MOUNTING
Can be clamped to an IV pole, placed on a hard surface, bed rail mount, or mounted to the rolling cart accessory.

Temperature Characteristics

RECOMMENDED OPERATING ENVIRONMENT

TEMPERATURE:
15°C-25°C

HUMIDITY:
Max relative humidity 80% (up to 31°C) decreasing linearly to 50% relative humidity at 40°C.

ALTITUDE:
Max 2,000m

TEMPERATURE CONTROL
Electronically controlled.

HEAT GENERATED

High fan setting:
1600 BTU/hr (average), 470 W (average)

Low fan setting:
1330 BTU/hr (average), 390 W (average)

OPERATING TEMPERATURES
Average temperatures at the end of the hose:

HIGH: 43° ± 1.5°C (109.4° ± 2.7°F)

MED: 38° ± 1.5°C (100.4° ± 2.7°F)

LOW: 32° ± 1.5°C (89.6° ± 2.7°F)

TIME TO REACH OPERATING TEMPERATURE
2 - 5 minutes (dependent on blanket model)

Time required for the contact surface temperature to heat up from 23 ± 2°C to 37°C (73 ± 2°F to 99°F).

STORAGE/TRANSPORT TEMPERATURE
-20°C to 45°C (-4°F to 113°F)

Store all components in a cool, dry place when not in use.

SAFETY SYSTEM

THERMOSTAT
Independent electronic circuit; thermal cutoff shuts the heater OFF to ensure hose end air remains below 46°C to 56°C; back-up over-temperature detection at hose inlet.

ALARM SYSTEM
Over-temperature (46°C to 56°C): red *Over-temp* indicator light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn OFF, and the user can no longer adjust the warming unit using the control panel.

FAULT:
Fault indicator light flashes, alarm sounds.

OVERCURRENT PROTECTION
Dual input fused lines.

Electrical Characteristics

HEATING ELEMENT
1400 W Resistive

LEAKAGE CURRENT
Meets UL 60601-1 and IEC 60601-1 requirements.

BLOWER MOTOR

OPERATING SPEED:
4,700 rpm (high fan setting)

4,100 rpm (low fan setting)

AIRFLOW:
Up to 48 cfm or 23 L/s

POWER CONSUMPTION
Peak: 1550 W

Average: 800 W

POWER CORD
15 ft., SJT, 3 cond., 13 A

15 ft., SJT, 3 cond., 15 A

4.6 m, HAR, 3 cond., 10 A

DEVICE RATINGS
110-120 VAC, 50/60 Hz, 11.7 A, or

220-240 VAC, 50/60 Hz, 7.2 A, or

100 VAC, 50/60 Hz, 15 A

FUSES

TYPE:
Fast acting ceramic fuses, 250 VAC

AMP RATING:
12 A (110 - 120 VAC)

8 A (220 - 240 VAC)

15 A (100 VAC)

OPERATING SPEED:
F (Fast Acting)

BREAKING CAPACITY:
15 A, 12 A: 750 A @ 250 Vac

15 A, 12 A: 10,000 A @ 125 Vac

8 A: 200 A @ 250 Vac

8 A: 10,000 A @ 125 Vac

CERTIFICATIONS

IEC 60601-1; IEC/EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No.601.1; EN 55011: EN 80601-2-35 and in accordance with Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device Directive as a Class IIb device.

CLASSIFICATION

MEDICAL — GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1; CAN/CSA-C22.2, No.601.1; ANSI/AAMI ES60601-1:2005 CSA-C22.2 No. 60601-1:08; EN 80601-2-35; Control No.4HZ8.

Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only, in accordance with UL 60601-1

DIAGNOSTICS

A qualified service technician can perform over-temperature detection system testing, temperature output testing, operating temperature calibration, and fault code troubleshooting.

Maintenance Checklist

FILTER INSPECTION

1. Remove and inspect the filter.
2. Return filter or replace as necessary.

Note: Replace every 12 months or every 500 hours (PN 90047).

CALIBRATE THE OPERATING TEMPERATURE

1. Attach the Model 22110 temperature test unit to the end of the warming unit hose.
2. Run in Ambient mode and high fan setting ( ) for 10 minutes.
3. Enter the calibration mode.
    a. Press the Alternate Mode button and Ambient button, together for approximately 3-seconds.
    b. Temperature measured at end of hose will display on LCD.
4. Adjust Bair Hugger warming unit displayed temperature so it matches test unit sensor as close as possible (± .1° increments).
    a. 32°C button lowers displayed temperature.
    b. 38°C button raises displayed temperature.

Note: Warming unit can only adjust ± 3.0°C. Try a different hose if more adjustment is required and call 3M technical support with results.

5. Save Settings – Press the Alternate Mode button to save your settings.

TEST OVER TEMPERATURE DETECTION SYSTEM

1. 1. Run in *Ambient* mode and *high fan* setting ( ) for 5 minutes.
2. Initiate over-temperature test
    a. Press the *Alternative Mode* and *43°C* button together for approximately 3-seconds.
    b. Wait as warming unit executes self test.
    c. Two beeps indicate test has completed.
3. Review Results
    a. Observe the temperature is 46°C to 56°C.
    b. Pass or fail indicated on display.

Maintenance Log

Date	Maintenance Action Performed

Maintenance Log

Date	Maintenance Action Performed